REMARKS

Claims 1-10 presently appear in this case. No claims have been allowed. The Official Action of November 13, 2000, has now been carefully studied. Reconsideration and allowance are respectfully urged.

Restriction

Restriction has been required between what the Examiner considers to be three patentably distinct inventions, namely:

Group I directed to a method for screening to detect DNA, presently comprising claims 1 and 2;

Group II directed to a method of screening to detect protein or antibody, presently comprising claims 1 and 3; and

Group III, directed to a method for screening pregnant women and nursing mothers, presently comprising claims 4-10.

While Invention I had been elected with traverse, applicants hereby respectfully traverse this restriction requirement. The restriction requirement is traversed on the basis of MPEP Section 803, second paragraph, which **requires** that there be a substantial burden in examining plural groups, even if the restriction requirement is otherwise correct. In the present case, all of the claims are directed to a method for screening by identifying a tax protein. Moreover, since it is assumed that the Examiner will search online rather than manually, and will search the SEQ ID Nos online, a search

which encompasses the DNA and method of making some would also include methods of using the enzyme. Since there is no serious burden, the restriction requirement should be withdrawn, and such is respectfully requested.

If the restriction requirement is maintained, it will be clear on the record that the PTO considers the two groups to be **patentably distinct** from one another, *i.e, prima facie* **non obvious** from one another. This means that a reference identical to the one group would not render the other group *prima facie* obvious.

Abstract

Submitted herewith is an Abstract of the Disclosure

Rejections under 35 U.S.C. 112

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 2 are said to be incomplete because the claims lack essential elements and steps for detecting the presence of DNA in a sample, and there is no definition of a "positive" test in the claims.

This rejection is respectfully traversed. With respect to detecting the presence of DNA in a sample, it is respectfully submitted that the present invention is not directed to an assay for the presence of DNA *per se*, and that one skilled in the art could readily determine an appropriate

test for detecting the presence of this DNA which encodes the HTLV-I Tax protein and/or the HTLV-II Tax protein. It should be noted that the specific primers and probes used, as disclosed in the specification beginning at page 18, line 25, are described in the literature, and that the conditions and temperature for PCR amplification and hybridization using these primers and probes were the same as those for HTLV Tax described in 1995.

The important aspect of the present invention is that blood can be screened for carriers or diseases or conditions related to HTLV-I and/or HTLV-II infection **solely** by screening the blood for the presence of HTLV-I Tax protein and/or the HTLV-II Tax protein, DNA which encodes the HTLV-I Tax protein and/or the HTLV-II Tax protein, or antibodies specific to the HTLV-I Tax protein and/or the HTLV-II Tax protein. **No other testing is required, because assaying for the HTLV-I Tax protein and/or the HTLV-II Tax protein is exquisitely sensitive for HTLV-I infection and/or HTLV-II infection.**

The present specification notes a page 8, lines 4-14, that blood which tests *tax* positive but structural protein negative is particularly harmful, as it has been found that recipients of such blood sera convert to *tax* positive, and the *tax* protein alone may cause health problems. By testing only for *tax* proteins, a conventional screening test, that for structural proteins of HTLV, can be eliminated and substituted

with the test of the present invention. The test of the present invention not only tests positive when the blood would have tested positive for the standard HTLV test, but will also find another factor, i.e., *tax*, which is not found in the standard HTLV test, but for which it is very important to screen out of blood intended for transfusion.

Art Rejections

Claims 1 and 2 are rejected under 35 U.S. C. 102(b) as being anticipated by Zucker-Franklin et al., *PNAS USA* 94(12):6403-6408, 1997. The Examiner alleges that this article discloses screening blood donors or potential blood donors for carriers of disease or conditions related to HTLV-I and/or the HTLV-II by screening to *tax* protein without input from any other tests results or screening test results.

This rejection is respectfully traversed. The sera tested in the description on page 646 had **tested negative for antibodies to HIV** [emphasis added], as disclosed at page 6404, left column, line 3. In addition, at page 6405, the individuals tested were HIV-negative methadone clinic attendees. Indeed, among the 63 individuals who were not expected to be HTLV-infected **on the basis of standard serologic tests**, there were seven whose cell lysates on PCT/Southern blot analysis revealed gag-I and/or pol-I in addition to Tax sequences (Table 2).

There is nothing in Zucker-Franklin et al. that suggests that the tax test be used in the absence of any other

testing, only that the tax test has been found to identify HIV infection where other tests have found no indication of infection. Indeed, on page 5406, right column, in the last sentence of the last paragraph, it is suggested that the inclusion of Tax in serologic test kits or more sensitive techniques incorporating simultaneous amplification of several relevant nucleic acid sequences by an automated system has been suggested elsewhere (28) could be introduced to screen our blood supply for HTLV more reliably.

The present inventors have concluded, based upon extensive testing of blood or other body fluids, that there is no requirement for input from any other test result to test positively for HTLV-I and/or HTLV-II.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By _____
Anne M. Kornbau
Registration No. 25,884

Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
AMK:nmp

"Version with Markings to Show Changes"

1. (Amended) A method of screening blood donors or potential blood donors for carriers of diseases or conditions related to HTLV-I and/or HTLV-II infection, comprising:

~~subjecting each blood sample from the donors or potential donors to a test for~~ wherein a positive test indicates the presence of:

(a) HTLV-I and/or HTLV-II Tax protein;

(b) DNA which encodes the HTLV-I Tax protein and/or ~~DNA which encodes the HTLV-II Tax protein, or~~

~~(c)~~ antibodies specific to the HTLV-I Tax protein and/or antibodies specific to the HTLV-II Tax protein~~, in the absence of any other screening test specifically provided to test for infection with either HTLV-I and/or HTLV-II~~; and

determining that the donor is a carrier of a disease or condition related to HTLV-I or HTLV-II infection when said subjecting step is positive, without input from any other test result.